REMARKS

1. Status of the Claims
Claims 1, 4-13, and 16-19 are currently pending.

2. Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1 and 10 because the term "the genome" is not clear. Applicants have amended claims 1 and 10 to define the genome as requested by the Examiner. The Examiner also rejected claim 11 as being indefinite for using the term "and/or". Applicants have made the appropriate correction. Reconsideration and removal of the rejection is respectfully requested.

3. Claim Rejections under 35 U.S.C. § 112, first paragraph

A. Written Description

The Examiner has again rejected existing claims 1, 4-13 and 16 and new claim 17-19 under 35 U.S.C. §112, first paragraph, for alleged lack of sufficient written description support. The Examiner has urged that the claims are directed to the use of a foreign nucleic acid molecule of `unspecified length, source and function" and that the Specification only describes two cDNAs which encode the AATP2 ADP/ATP translocator from *Arabidopsis* and the AATP 1 from *S. tuberosum.* The Examiner has argued that the Specification does not provide adequate written support for the use of any foreign nucleic acid molecule. Applicants respectfully traverse.

While the Examiner has set forth the correct standard to determine whether a Specification provides adequate written description support for a claimed invention, Applicants submit that the Examiner has completely misapplied the standards to the present application. The Examiner seems focused only on whether the specification and claims describe some sufficient amount of sequence information. But this is not the type of case where that is the key issue. This is not a case where the Applicants claim to have isolated and

sequenced a newly identified gene. The present Applicants have essentially found a previously unknown use for a category of already known genes, namely the preparation of plants with modified or altered starch content. In such a situation, Applicants should be entitled to broad coverage, without being limited to some generic structural definition.

The present inventors were the first to discover that an increase in the activity of the ADP/ATP translocator leads to an increase in the starch contents in the corresponding transgenic plants. The up-regulation in ADP/ATP translocator activity was also surprisingly found to affect the molecular composition of the starch produced by the transformed plants. Although the examples in the Specification discuss the use of a particular foreign nucleic acid molecule in the invention (specifically from *Arabidopsis* as a model plant), the Specification clearly states that any nucleic acid molecule encoding an ADP/ATP translocator, which, after expression, is localized in the inner membrane of plastids, can be used to transform plant cells to achieve the results of the present invention.

While the Specification describes working examples using the genes from *Arabidopsis*, it is fundamental patent law that it is not necessary for the claims to be limited to the working examples. A person of ordinary skill in the art, after reading the disclosure, would understand that Applicants clearly recognized and taught that any foreign nucleic acid molecule encoding an ADP/ATP translocator, which is localized to the plastid, would achieve the desired purpose. In other words, the skilled artisan would realize that transforming a plant cell with such a foreign nucleic acid molecule would yield a plant cell which exhibits altered starch production and/or content. The Examiner has acknowledged that the Specification describes two cDNAs from *Arabidopsis* which encode ADP/ATP translocator proteins. However, the Examiner discounts the other examples of foreign nucleic acid molecules encoding ADP/ATP translocators from potato and bacteria described in the Specification arguing that "it is unclear whether the references teach genes or merely enzymes" and that Applicants have failed to provide a comparison of "functional features". The Examiner also appears to suggest that Applicants' reliance on these publications is misplaced or improper because these sequences are not set forth in the sequence listing and are not incorporated by reference.

Again, Applicants submit that the Examiner's objection is misplaced for a case of this type. The Specification sets forth the common functional feature or characteristic that must be shared by the genus of foreign nucleic acid molecules. The last paragraph on page 6 of the Specification clearly states that a "plastidial ATP/ADP translocator is a transport protein which is localized in the inner membrane of plastids ... and which catalyzes the transport of ATP into plastids and of ADP out of the plastids (see also page 7, line 12). The Specification also provides many examples of known foreign nucleic acid molecules that possess the desired activity. Page 4, paragraph 2 of the Specification explicitly refers to three sequences identified by their Genebank Accession Numbers: *X94626,* Z49227 and Y10821). These sequences are publicly known and available and a quick search of the NCBI database reveals that these three sequences correspond to the *A. thaliana* mRNA for AATP2, *A. thaliana* mRNA for adenine nucleotide translocase and *Solarium tuberosum* mRNA for plastidic ATP/ADP transporter, respectively (see attached). A person of ordinary skill in the art would, therefore, recognize that the reference to these particular accession numbers referred to nucleotide sequences, not enzymes. The Specification also cites to Williamson et al., which describes another ADP/ATP translocator from *Rickettsia.* The disclosure on page 7, lines 1-5 discusses the great similarity shared between the cDNA encoding an ADP/ATP translocator from Arabidopsis and the ADP/ATP translocator from *Rickettsia prowazekii.*

The Examiner argues that Applicants have failed to make a comparison of functional features. Applicants disagree but note that the foreign nucleotide sequences discussed within the Specification have all been acknowledged in the literature as encoding plastidial ADP/ATP translocator proteins. As such, Applicants do not believe they are required to demonstrate that these nucleotide sequences share a common functionality. Those skilled in that art already recognize that common functionality.

Finally, a person of ordinary skill in the art would be able to select and identify other foreign nucleic acid molecules encoding plastidial ADP/ATP translocator proteins using convention techniques such as heterologous screening (see page 4, para. 2). The activity of an ADP/ATP translocators encoded by candidate foreign nucleic acid molecules can be determined using the assay technique outlined in the last paragraph on page 5 of the Specification.

ADP/ATP translocator activity can be determined by monitoring the increase in the ATP transport rate into the reconstituted proteoliposomes derived from yeast or E. *coli* cells expressing an ADP/ATP translocator. Therefore, a person of ordinary skill in the art would conclude that the Specification describes several examples of foreign nucleic acid molecules encoding a plastidial ADP/ATP translocator and also describes how to select and isolate other foreign nucleic acid molecules for use in the invention. Accordingly, Applicants submit that Specification provides adequate written description support for the use of any foreign nucleic acid molecule encoding a plastidial ADP/ATP translocator for use in the invention. Reconsideration and removal of the rejection is respectfully requested.

B. Enablement

The Examiner has also again rejected claims 1, 4-13 and 16 for lack of enablement. The Examiner acknowledges that the Application is enabled for a method for the production of transgenic potato plants transformed with the AATP 1-cDNA gene from *Arabidoposis,* which exhibit an increased yield of starch and percent amylose content. However, the Examiner maintains that the application does not enable claims for a method for the production for transgenic plants transformed with a foreign nucleic acid molecule of undefined source, length and function, exhibiting an increased yield of starch and percent amylose content. The Examiner states that Applicants' prior arguments have been considered but have been found unpersuasive. The Examiner specifically comments on Applicants' arguments with respect to the Willmitzer and Anderson et al. references but maintains that these references support his conclusion that the present claims are not enabled. Applicants respectfully disagree.

The teachings of the instant application have been summarized above. However, Applicants believe that it is worthwhile to point out that while the examples in the Specification describe a method for producing potato plants using the AATP 1 cDNA from *Arabidopsis*, the Specification also describes various methods well known to persons of ordinary skill in the art which would enable the production of plants of species other than potato and expressing an plastidial ADP/ATP

translocator protein other than AATP 1. This fact appears to have been completely overlooked by the Examiner. As discussed above, the skilled artisan would be able to establish whether a given nucleotide sequence that would encode an ADP/ATP translocator by (1) expressing this nucleotide sequence in *E. coli* or yeast and (2) checking the activity of the expressed product in proteoliposome reconstitution experiments as described on page 7, lines 7-10 of the Specification. The skilled artisan could also locate other nucleotide sequences encoding ADP/ATP translocators by searching sequence databases, including structure prediction databases like e.g. Pfam. As the claims refer to plastidial ADP/ATP translocators, the skilled artisan could employ well-known techniques in the art to ensure that the respective protein, when expressed in plants, is transported to the plastids (see page 4, line 16 et seq. in the Specification). The various techniques the skilled artisan could employ are generally described on page 17, lines 3-21 and on page 5, line 21 to page 6, line 3 of the Specification.

In the present Office Action, the Examiner has rejected Applicants' arguments with respect to the disclosure of the Willmitzer reference and has maintained that Willmitzer is "unambiguous in teaching unpredictability of manipulating starch metabolism by transformation". Applicants respectfully disagree and would like to point out that the situation in Willmitzer is not directly comparable to the present situation. Willmitzer hypothesized that the downregulation of a branching enzyme would lead to increased amylose content. This hypothesis could not be confirmed in an experiment. In contrast, the present inventors have demonstrated by experimental evidence that the overexpression of a plastidial ADP/ATP translocator will lead to an increased yield. There is no ambiguity with respect to the data described in the instant application. Accordingly, a person of ordinary skill in the art could reasonably conclude that transforming other plant species in a similar fashion would lead to a similar result.

The Examiner also places undue emphasis on the teachings of Anderson in rejecting the claims for lack of enablement. In Applicants' previous response, Applicants have argued that Anderson does not teach how isoforms of a starch metabolic enzyme is an unpredictable factor in starch modification via transformation. In rejecting this argument, the Examiner states that the Anderson reference clearly refers to the "presence of tissue specific expression of either the

same gene or different sized and unique isoforms" at page 170 of the reference. The Examiner also comments on Applicants' failure to address the Examiner's arguments with respect to the polyploidal nature of many high production starch crop plants and the likely presence of multiple isoforms therein, as well as the nature of specific tissue specific regulation articulated in the Anderson reference. Finally, the Examiner argues that no demonstration of altered oil content in oilstoring or starch-storing plants has been demonstrated.

First, Applicants would like to point out that the potato plant (Desiree) employed in the examples described in the Specification is a tetraploid, i.e. a polyploid, and is an example of a high starch crop production plant. Applicants would also like to point out that the experiments described in the application have shown that the invention does indeed work for its desired purpose. Although not specifically discussed in their last response, Applicants submit that the following points would be apparent to the skilled artisan. Namely, that cultivated potato varieties such as Désiree are known per se to have a very heterogeneous genome. Thus, the presence of multiple enzyme isoforms in this variety are highly unlikely. Furthermore, the skilled artisan would recognize that many enzymes in potato are regulated in a tissue-specific manner. While the Examiner may contend that there is a high degree of unpredictability that an increased yield or change in amylose content can be achieved by overexpressing a plastidial ADP/ATP translocator in crops of a complex nature, there is no denying that this is exactly what the present inventors have done and have described in their application. This teaching would be accepted by persons of ordinary skill in the art despite alleged doubts expressed in older references. Simply stated, the present application provides the necessary teaching which would allow a person of ordinary skill in the art to (1) reproduce the results achieved by the present inventors and (2) similarly transform other plants to obtain similar results with a reasonable amount of certainty.

Applicants would also like to comment on the tissue-specific regulation argument advanced by the Examiner. It should be emphasized that the claims are directed to a transformed plant in which an ADP/ATP translocator is overexpressed. The spatial and developmental regulation of gene expression referred to in Anderson might at best explain results obtained when antisense inhibition of a given gene (like the approach described in Willmitzer) does not work in certain tissues or at certain developmental stages. However, in the present case, over-expression

of an ADP/ATP translocator leads to the presence of this protein at any time and in any tissue provided a corresponding constitutive promoter is used. This is a dominant effect and leads to an increased import of ATP into the plastids, independently of tissue type and developmental stage. Therefore, Applicants submit that it is difficult to imagine how tissue- and/or developmental stage-specific alleles of an ADP/ATP translocator could influence the additional presence and/or activity of the over-express protein.

The present application clearly demonstrates that the increase of ATP/ADP translocator activity leads to an increase of starch and an increase of the amylase content. As noted above, the Specification describes foreign nucleic acid molecules, which may be used to practice the invention and other suitable foreign nucleic acid molecules would be apparent to person of ordinary skill in the art. Applicants have described how to make and use the claimed invention and have set forth examples to demonstrate that the invention works. Applicants are not, however, required to describe each and every foreign nucleic acid molecule that may be used to practice the full scope of the invention. A person of ordinary skill in the art can isolate and identify suitable foreign nucleic acid molecules to practice the invention using conventional techniques without undue experimentation.

Applicants submit that the foregoing remarks demonstrate that the instant application is fully described and enable by the Specification. Accordingly, Applicants respectfully request reconsideration and removal of the written description and enablement rejections in view of the Willmitzer and Anderson references.

Favorable consideration and early allowance of all the claims is respectfully requested.

Should there by any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,300) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants respectfully petition for a one (1) month extension of time for filing a response in connection with the present application and the required fee of $110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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0147-0215P

Attachments: NCBI Printouts (3)

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(Date of Deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Susan M. Kingsworthy
(Signature)

Nov 3 2003
(Date of Signature)

1: X94626. A.thaliana mRNA f...[gi:1707363] Linl

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  TITLE     Occurrence of two plastidic ATP/ADP transporters in Arabidopsis
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  JOURNAL   Submitted (03-JAN-1996) E. Neuhaus, Universitaet Osnabrueck,
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  JOURNAL   Submitted (05-MAY-1995) Kampfenkel K.K., Universiteit Gent,
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1: Y10821. Solanum tuberosum...[gi:4138582] Linl

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LOCUS       STPLATDTR               2300 bp    mRNA    linear   PLN 22-JAN-1999
DEFINITION  Solanum tuberosum mRNA for plastidic ATP/ADP-transporter.
ACCESSION   Y10821
VERSION     Y10821.1  GI:4138582
KEYWORDS    plastidic ATP/ADP-transporter.
SOURCE      Solanum tuberosum (potato)
  ORGANISM  Solanum tuberosum
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicots;
            asterids; lamiids; Solanales; Solanaceae; Solanum.
REFERENCE   1
  AUTHORS   Tjaden,J., Mohlmann,T., Kampfenkel,K., Henrichs,G. and Neuhaus,H.E.
  TITLE     Altered plastidic ATP/ADP-transporter activity influences potato
            (Solanum tuberosum L.) tuber morphology, yield and composition of
            tuber starch
  JOURNAL   Plant J. 16, 531-540 (1998)
REFERENCE   2
  AUTHORS   Neuhaus,E.
  TITLE     Direct Submission
  JOURNAL   Submitted (24-JAN-1997) E. Neuhaus, University of Osnabrueck, Plant
            Physiology, Barbarastrasse 11, D-49069 Osnabrueck, FRG
  REMARK    Revised by [3]
REFERENCE   3  (bases 1 to 2300)
  AUTHORS   Neuhaus,E.
  TITLE     Direct Submission
  JOURNAL   Submitted (06-JAN-1999) E. Neuhaus, University of Osnabrueck, Plant
            Physiology, Barbarastrasse 11, D-49069 Osnabrueck, FRG
COMMENT     On Jan 9, 1999 this sequence version replaced gi:2326873.
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PSSPRSL"

ORIGIN

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